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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/697,295  | 10/31/2003  | Se Ho Park           | 123034-05004796     | 8427             |
| 43569   | 7590        | 03/13/2006           | EXAMINER            |                  |
| MAYER, BROWN, ROWE & MAW LLP<br>1909 K STREET, N.W.<br>WASHINGTON, DC 20006 |             |                      | CALAMITA, HEATHER   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |

1637

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                            |  |                     |  |
|------------------------------|----------------------------|--|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>     |  | <b>Applicant(s)</b> |  |
|                              | 10/697,295                 |  | PARK ET AL.         |  |
|                              | <b>Examiner</b>            |  | <b>Art Unit</b>     |  |
|                              | Heather G. Calamita, Ph.D. |  | 1637                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/31/03; 10/21/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claim 1 includes the recitation "characterized in that the step of changing a primer annealing temperature and an extension time per cycles of constant period." This limitation is unclear with respect to the metes and bounds of the claimed subject matter. It is not clear from the claim language what constitutes "constant period." It is unclear to what period this refers. A more specific explanation of the claimed subject matter would be more favorably considered.

Claim 6 includes the recitation "wherein said annealing temperature increases by a value of  $(Tm\_max - Tm\_min)$  for 1 cycle." It is unclear to what specific values the  $Tm\_max$  and  $Tm\_min$  refer. It is unclear if Applicant is referring to the  $Tm$  of the primer or the template.

### *Claim Interpretation*

2. Claim 1 includes the limitation "characterized in that the step of changing a primer annealing temperature and an extension time per cycles of constant period." This limitation is unclear with respect to the metes and bounds of the claimed subject matter. It is not clear from the claim language what constitutes "constant period." It is unclear to what period this refers. With regard to the art rejections, the recitation is interpreted as meaning either the annealing period or the extension period. Additionally, claim 1 is interpreted as not necessarily requiring the two amplified products be in the same tube.

*Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Khaled et al. (FEMS Microbiology Letters, 1997).

With regard to claim 1, Khaled et al. teach a method for performing multiplex PCR for having at least two amplified DNA products from samples positioned within a PCR equipment, characterized in that the step of changing a primer annealing temperature and an extension time per cycles of constant period (see p. 193 paragraph 2.3 and table 2, where multiple primers are used to produce multiple DNA products. Khaled et al. teach raising the annealing temperature from 40°C to 50°C and changing the extension time from 30 seconds to 8 minutes).

With regard to claim 2, Khaled et al. teach the samples are genomic DNA (see p. 192 paragraph 2.2, where the total genomic DNA was extracted from the bacteria and used as a template).

With regard to claim 4, Khaled et al. teach the PCR equipment can change the set temperature and time parameters per cycles of the constant period (see p. 193 paragraph 2.3, where Khaled discloses the use of FTS-1 thermal sequencer).

With regard to claim 5, Khaled et al. teach the annealing temperature and extension time increase per cycles of constant period (see p. 193 paragraph 2.3 and table 2, where multiple primers are used to produce multiple DNA products. Khaled et al. teach raising the annealing temperature from 40°C to 50°C and changing the extension time from 30 seconds to 8 minutes).

*Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khaled et al. (FEMS Microbiology Letters, 1997) in view of Burckhardt (USPN 5,501,963, March 1996).

The teachings of Khaled et al. are described previously.

Khaled et al. do not teach diluted blood or a sample volume of less than a microliter.

With regard to claims 3 and 7, Burckhardt teaches diluted blood and a sample volume of less than a microliter (see col. 16 line 4 and table 4, where the blood sample was diluted to various concentrations).

One of ordinary skill in the art at the time the invention was made would have been motivated to dilute the sample as taught by Burckhardt with the method of PCR as taught by Khaled in order to conserve the sample for future applications. Burckhardt teaches one microliter of whole blood is sufficient for amplification (see col. 16 line 4). It would have been prima facie obvious to use a small sample volume as taught by Burckhardt with the method of PCR as taught by Khaled in order to conserve sample for use in future applications or analysis.

#### *Summary*

4. No claims were allowable.

#### *Correspondence*

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

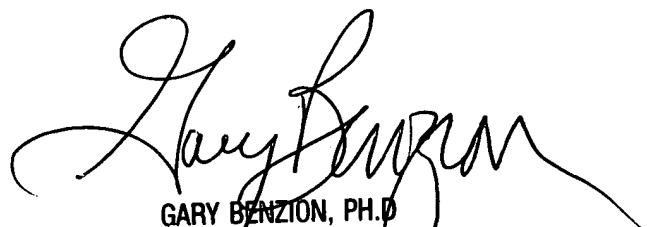
Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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